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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gray Cary Ware & Freidenrich LLP			EXAMINER	
Suite 1100 4365 Executive Drive San Diego, CA 92121-2133		BERTOGLIO, VALARIE E		
San Diego, CA	92121-2133		ART UNIT PAPER NUMBE	
			1632	6
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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

		Application No.	Applicant(s)			
•		10/003.630	WONG ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Valarie Bertoglio	1632			
Period fo	The MAILING DATE of this communication app or Reply					
THE I - Exter after - If the - If NO - Failu - Any r	DRIEND STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. AND	36(a). In no event, however, may a reply be ti within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS from	mely filed ys will be considered timely. n the mailing date of this communication.			
1)	Responsive to communication(s) filed on	_·				
2a)	This action is FINAL. 2b)⊠ Thi	is action is non-final.				
3)□ Dispositi	Since this application is in condition for allowa closed in accordance with the practice under lon of Claims	ince except for formal matters, p Ex parte Quayle, 1935 C.D. 11,	rosecution as to the merits is 453 O.G. 213.			
4)⊠	Claim(s) 1-56 is/are pending in the application					
	a) Of the above claim(s) is/are withdraw	vn from consideration.				
5)	Claim(s) is/are allowed.					
6)[6) Claim(s) is/are rejected.					
7)	Claim(s) is/are objected to.					
	Claim(s) <u>1-56</u> are subject to restriction and/or e on Papers	lection requirement.				
9)[] 1	he specification is objected to by the Examiner	•				
10)□ T	he drawing(s) filed on is/are: a) accep	ted or b)□ objected to by the Exa	miner.			
	Applicant may not request that any objection to the					
11) 🔲 T	he proposed drawing correction filed on	is: a) ☐ approved b) ☐ disappro	oved by the Examiner.			
	If approved, corrected drawings are required in repl					
	he oath or declaration is objected to by the Exa	miner.				
Priority u	nder 35 U.S.C. §§ 119 and 120					
13)	Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)-(d) or (f).			
	All b) Some * c) None of:					
	I. Certified copies of the priority documents					
	2. Certified copies of the priority documents	have been received in Application	on No			
	3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 1.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a)	☐ The translation of the foreign language prov knowledgment is made of a claim for domestic	risional application has been rec	eived.			
Attachment(
) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) stion Disclosure Statement(s) (PTO-1449) Paper No(s)	4) Interview Summary 5) Notice of Informal F 6) Other:	(PTO-413) Paper No(s) Patent Application (PTO-152)			
Date of and To-	toward Office					

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1,2,4 and 5, drawn to a method of modulating the production of Aβ11-40/42 peptide fragments comprising contacting a sample or cell containing BACE1 and APP with a BACE-1 modulating agent in vitro wherein the agent is an antibody, classified in class 530, subclass 387.1.
- II. Claims 1-3 and 5, drawn to a method of modulating the production of Aβ11-40/42 peptide fragments comprising contacting a sample or cell containing BACE1 and APP with a BACE-1 modulating agent in vivo wherein the agent is an antibody, classified in class 424, subclass 130.1.
- III. Claims 1,2,4 and 5, drawn to a method of modulating the production of Aβ11-40/42 peptide fragments comprising contacting a sample or cell containing BACE1 and APP with a BACE-1 modulating agent in vitro wherein the agent is an antisense molecule, classified in class 536, subclass 24.5.
- IV. Claims 1-3 and 5, drawn to a method of modulating the production of Aβ11-40/42 peptide fragments comprising contacting a sample or cell containing BACE1 and APP with a BACE-1 modulating agent in vivo wherein the agent is an antisense molecule, classified in class 514, subclass 44.
- V. Claims 6-9, drawn to a method for identifying a compound that inhibits BACE1 expression or activity in vitro wherein BACE1 is a polypeptide, classified in class 435, subclass 4.
- VI. Claims 6-9, drawn to a method for identifying a compound that inhibits BACE1 expression or activity in vivo wherein BACE1 is a polypeptide, classified in class 424, subclass 9.2.

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VII. Claims 6-9, drawn to a method for identifying a compound that inhibits BACE1 expression or activity in vitro wherein BACE1 is a polynucleotide, classified in class 435, subclass 4.

- VIII. Claims 6-9, drawn to a method for identifying a compound that inhibits BACE1 expression or activity in vivo wherein BACE1 is a polynucleotide, classified in class 424, subclass 9.2.
- IX. Claims 10 and 11, drawn to a compound that inhibits BACE1, unclassifiable.
- X. Claims 12-16,20-23 and 41-44, drawn to a method for diagnosing a subject having or at risk for an Aβ11-40/42 accumulation disease comprising measuring levels of BACE-1 mRNA and a kit comprising a nucleic acid probe, classified in class 424:536, subclass 9.1:24.3.
- XI. Claims 12-14, 17-23, and 41-56, drawn to a method for diagnosing a subject having or at risk for an Aβ11-40/42 accumulation disease comprising measuring levels of BACE-1 polypeptide using an agent that binds the polypeptide and a kit comprising an antibody specific for BACE-1, classified in class 424;530, subclass 9.1:387.1.
- XII. Claims 24-29 and 41-44, drawn to a method for diagnosing a subject having or at risk for Alzheimer's disease comprising measuring levels of Aβ11-40/42 using an agent that binds Aβ11-40/42 and a kit comprising an antibody specific for Aβ11-40/42, classified in class 424:530, subclass 9.1:387.1.
- XIII. Claims 30-33, drawn to a transgenic non-human animal having a transgene disrupting expression of BACE1, classified in class 800;800, subclass 8;12.
- XIV. Claims 34 and 37-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of a wild-type

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organism contacted with the agent to that of a BACE-1 knockout organism, classified in class 800, subclass 3.

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- XV. Claims 34-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of the organism contacted with the agent to that of a BACE-1 knockout organism wherein the knockout organism is transgenic for overexpression of BACE1, classified class 800, subclass 3.
- XVI. Claims 34-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of the organism contacted with the agent to that of a BACE-1 knockout organism wherein the knockout organism is transgenic for overexpression of APP, classified in class 800, subclass 3.
- XVII. Claims 34-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of the organism contacted with the agent to that of a BACE-1 knockout organism wherein the knockout organism is transgenic for overexpression of Aβ1-40, classified in class 800, subclass 3.
- XVIII. Claims 34-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of the organism contacted with the agent to that of a BACE-1 knockout organism wherein the knockout organism is transgenic for overexpression of Aβ1-42, classified in class 800, subclass 3.
- XIX. Claims 34-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of the organism

contacted with the agent to that of a BACE-1 knockout organism wherein the knockout organism is transgenic for overexpression of A β 11–40, classified in class 800, subclass 3.

- XX. Claims 34-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of the organism contacted with the agent to that of a BACE-1 knockout organism wherein the knockout organism is transgenic for overexpression of Aβ11–42, classified in class 800, subclass 3.
- XXI. Claims 34-40, drawn to a method of identifying an agent that modulates the expression or activity of BACE1 by comparing the phenotype of the organism contacted with the agent to that of a BACE-1 knockout organism wherein the knockout organism is transgenic for overexpression of a combination of BACE1, APP, Aβ1-40, Aβ1-42, Aβ11-40, or Aβ11-42, classified in class 800, subclass 3.
- XXII. Claim 44, drawn to a method for predicting the therapeutic effectiveness of a compound comprising measuring the accumulation of Aβ11–40/42 peptide fragments in a subject before and after treatment with the compound, classified in class 424, subclass 9.2.
- XXIII. Claim 44, drawn to a method for predicting the therapeutic effectiveness of a compound comprising measuring the accumulation of BACE1 polynucleotide in a subject before and after treatment with the compound, classified in class 424, subclass 9.2.
- XXIV. Claim 44, drawn to a method for predicting the therapeutic effectiveness of a compound comprising measuring the accumulation of BACE1 peptide in a

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subject before and after treatment with the compound, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

The methods of each of Inventions I-IV are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Invention I are in vitro methods of using an antibody to modulate the production of A β 11-40/42. The methods of Invention II are in vivo methods of using an antibody to modulate the production of A β 11-40/42. The methods of Inventions III and IV are in vitro and in vivo, respectively, methods of using an antisense molecule to modulate the production of A β 11-40/42. Each invention is classified separately. The burden required to search any of Groups I-IV together would be undue.

The methods of each of Inventions I-IV and each of Inventions V-VIII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of inventions I-IV are drawn to modulating production of Aβ11-40/42 using antibodies or antisense molecules. The methods of Inventions V-VIII are drawn to identifying peptide and small molecule inhibitors of BACE-1. Each of Inventions I-IV are classified separately from each of Inventions V-VIII. The burden required to search any of Groups I-IV together with any of Groups V-VIII would be undue.

Each of Inventions I-IV and Invention IX are patentably distinct because the methods of Inventions I-IV can be used to modulate the production of A β 11-40/42 in vitro using compounds that act through a variety of mechanisms in addition to inhibiting BACE-1. The inhibitor of

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BACE-1 can be used either in vitro or in vivo to modulate gene expression or treat disease. The burden required to search any of Inventions I-IV together with Invention IX would be undue.

The methods of each of Inventions I-IV and each of Inventions X-XII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of inventions I-IV are drawn to modulating production of Aβ11-40/42 using antibodies or antisense molecules. The methods of Inventions X-XII are drawn to diagnosing a subject for Aβ11-40/42. Each of Inventions I-IV is classified separately from each of Inventions X-XII. The burden required to search any of Groups I-IV together with any of Groups X-XII would be undue.

Each of Inventions I-IV and Invention XIII are patentably distinct because the methods of Inventions I-IV can be used to modulate the production of Aβ11-40/42 in vitro using compounds that act through a variety of mechanisms in addition to inhibiting BACE-1. The transgenic animal comprising a disruption in BACE-1 can be used to determine the in vivo role of BACE-1. The methods are not necessary for the animal and the animal is not necessary for the methods. The methods and the animal are classified differently. The burden required to search any of Inventions I-IV together with Invention XIII would be undue.

Each of Inventions I-IV and each of Inventions XIV-XXI are patentably distinct because the methods of Inventions I-IV can be used to modulate the production of Aβ11-40/42 in vitro using compounds that act through a variety of mechanisms in addition to inhibiting BACE-1 while the methods of Inventions XIV-XXI use various transgenic animals to identify agents that modulate BACE-1 in vivo. The methods of Inventions I-IV are not necessary for the methods of using the animals and the methods of using the animals are not necessary for the methods of Inventions I-IV. The methods of Inventions I-IV and those of Inventions XIV-XXI are classified

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differently. The burden required to search any of Inventions I-IV together with any of Inventions XIV-XXI would be undue.

Each of Inventions I-IV and each of Inventions XXII-XXIV are patentably distinct because the methods of Inventions I-IV can be used to modulate the production of Aβ11-40/42 in vitro using compounds that act through a variety of mechanisms in addition to inhibiting BACE-1 while the methods of Inventions XXII-XXIV are used to determine the efficacy of a treatment in vivo. The methods of Inventions I-IV are not necessary for the methods of Inventions XX-XXII and the methods of Inventions XXII-XXIV are not necessary for the methods of Inventions I-IV. The methods of Inventions I-IV and those of Inventions XXII-XXIV are classified differently. The burden required to search any of Inventions I-IV together with any of Inventions XXII-XXIV would be undue.

The methods of each of Inventions V-VIII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Inventions V and VII are in vitro methods of identifying a compound that inhibits BACE-1 expression or activity wherein BACE-1 is a polypeptide (Invention V) or a polynucleotide (Invention VII). The methods of Inventions VI and VIII are in vivo methods of identifying a compound that inhibits BACE-1 expression or activity wherein BACE-1 is a polypeptide (Invention VII) or a polynucleotide (Invention VIII). Because the method steps for in vitro and in vivo testing are distinct and require different starting materials and the compounds being tested are classified differently, the burden required to search any of Groups V-VIII together would be undue.

Each of Inventions V-VIII, and Invention IX are patentably distinct because the methods of Inventions V-VIII used to identify inhibitors of BACE-1 while the compounds of Invention IX

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can be used either in vitro or in vivo to modulate gene expression or treat disease. The methods are not necessary to make the compound and the compounds are not necessary for the methods. The burden required to search any of Inventions V-VIII together with Invention IX would be undue.

The methods of each of Inventions V-VIII and Inventions X-XII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of inventions V-VIII are drawn identifying BACE-1 inhibitors. The methods of Inventions X-XII are drawn to diagnosing a subject for an Aβ11-40/42 accumulation disorder. Each of Inventions V-VIII is classified separately from each of Inventions X-XII. The burden required to search any of Groups V –VIII together with any of Groups X-XII would be undue.

Each of Inventions V-VIII, and Invention XIII are patentably distinct because the methods of Inventions V-VIII used to identify inhibitors of BACE-1 while the transgenic animal comprising a disruption in BACE-1 can be used to determine the in vivo role of BACE-1. The methods are not necessary for the animal and the animal is not necessary for the methods. The methods and the animal are classified differently. The burden required to search Inventions V-VIII together with Invention XIII would be undue.

Each of Inventions V-VIII and each of Inventions XIV-XXI are patentably distinct because the methods of Inventions V-VIII can be used to identify compounds that modulates BACE-1 activity while the methods of Inventions XIV-XXI use various transgenic animals to identify agents that modulate BACE-1 in vivo. The methods are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Inventions

V-VIII use in vitro method steps while Inventions XIV-XXI use in vivo methods. The methods of Inventions V-VIII are not necessary for the methods of using the animals and the methods of using the animals are not necessary for the methods of Inventions V-VIII. The methods of Inventions V-VIII and those of Inventions XIV-XXI are classified differently. The burden required to search Inventions V-VIII together with any of Inventions XIV-XXI would be undue.

Each of Inventions V-VIII and each of Inventions XXII-XXIV are patentably distinct because the methods of Inventions V-VIII can be used to identify compounds that modulates BACE-1 activity while the methods of Inventions XXII-XXIV are used to determine the efficacy of a treatment in vivo. The methods of Inventions V-VIII are not necessary for the methods of Inventions XX-XXII and the methods of Inventions XXII-XXIV are not necessary for the methods of Inventions V-VIII. The methods of Inventions V-VIII and those of Inventions XXII-XIV are classified differently. The burden required to search any of Inventions V-VIII together with any of Inventions XXII-XIV would be undue.

Invention IX and each of Inventions X-XII are patentably distinct because the compounds of Invention IX can be used to inhibit BACE-1 activity or expression while the methods of Inventions X-XII can be used to diagnose disease. The methods are not necessary to make the compound and the compounds are not necessary for the methods. The burden required to search Invention IX or any of Inventions X-XII together would be undue.

Invention IX Invention XIII are patentably distinct because the compounds of Invention IX can be used to inhibit BACE-1 activity or expression in vitro while the transgenic animal comprising a disruption in BACE-1 can be used to determine the in vivo role of BACE-1. The compound is not necessary for the animal and the animal is not necessary for the compound. The compound and the animal are classified differently. The burden required to search Inventions IX and XIII together would be undue.

Inventions IX and each of Inventions XIV-XXI are patentably distinct because the compounds of Invention IX can be used to inhibit BACE-1 activity or expression in vitro while the methods of Inventions XIV-XXI use various transgenic animals to identify agents that modulate BACE-1 in vivo. The compound is not necessary for the methods of using the animals and the methods of using the animals are not necessary for compounds. The compound and the methods of using transgenic animals are classified differently. The burden required to search Invention IX together with any of Inventions XIV-XXI would be undue.

Invention IX and each of Inventions XXII-XXIV are patentably distinct because the compounds of Invention IX can be used to inhibit BACE-1 activity or expression in vitro while the methods of Inventions XXII-XXIV are used to determine the efficacy of a treatment in vivo. The compounds Invention IX are not necessary for the methods of Inventions XXII-XXIV and the methods of Inventions XXII-XXIV are not necessary for the compounds. The compounds of Invention IX and the methods of Inventions XXII-XXIV are classified differently. The burden required to search Invention IX together with any of Inventions XXII-XXIV would be undue.

The methods of each of Inventions X-XII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Invention X comprise measuring levels of BACE-1 mRNA. The methods of Invention XI comprise measuring levels of BACE-1 polypeptide. Invention XII comprises measuring levels of Aβ11-40/42. The assays used in each invention are different and require different detective reagents and methodologies, which are classified differently. The burden required to search any of Groups X-XII together would be undue.

Each of Inventions X-XII and Invention XIII are patentably distinct because the methods of Inventions X-XII are can be used to diagnose an A β 11-40/42 accumulation disease while the

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transgenic animal comprising a disruption in BACE-1 can be used to determine the in vivo role of BACE-1. The methods are not necessary for the animal and the animal is not necessary for the methods. The methods and the animal are classified differently. The burden required to search any of Inventions X-XII and Invention XIII together would be undue.

Each of Inventions X-XII and each of Inventions XIV-XXI are patentably distinct because the methods of Inventions X-XII can be used to diagnose an Aβ11-40/42 accumulation disease while the methods of Inventions XIV-XXI use various transgenic animals to identify agents that modulate BACE-1 in vivo. The methods are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Inventions X-XII are not necessary for the methods of using the animals and the methods of using the animals are not necessary for the methods of Inventions X-XII. The methods of Inventions X-XII and those of Inventions XIV-XXI are classified differently. The burden required to search Inventions X-XII together with any of Inventions XIV-XXI would be undue.

Each of Inventions X-XII and each of Inventions XXII-XXIV are patentably distinct because the methods of Inventions X-XII can be used to diagnose an Aβ11-40/42 accumulation disease while the methods of Inventions XXII-XXIV are used to determine the efficacy of a treatment in vivo. The methods of Inventions X-XII are not necessary for the methods of Inventions XXII-XXIV and the methods of Inventions XXII-XXIV are not necessary for the methods of Inventions X-XII. The methods of Inventions X-XII and those of Inventions XXII-XIV are classified differently. The burden required to search either of Inventions X-XII together with any of Inventions XXII-XXIV would be undue.

Invention XIII and each of Inventions XIV-XXI are patentably distinct because the animal of Invention XIII can be used as a model of disease to study disease processes while the

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methods of Inventions XIV-XXI use various transgenic animals to identify agents that modulate BACE-1 in vivo. The animal of Inventions XIII is not necessary for identifying agents and the methods of identifying agents are not necessary for the animal. The animal of Invention XIII and the methods of Inventions XIV-XXI are classified differently. The burden required to search Invention XIII together with any of Inventions XIV-XXI would be undue.

Invention XIII and each of Inventions XXII-XXIV are patentably distinct because the animal of Invention XIII can be used as a model of disease to study disease processes while the methods of Inventions XXII-XXIV are used to determine the efficacy of a disease treatment in vivo. The animal of Invention XIII not necessary for the methods of Inventions XXII-XXIV and the methods of Inventions XXII-XXIV are not necessary for the animal. The animal of Invention XIII and the methods of Inventions XXII-XIV are classified differently. The burden required to search Invention XIII together with any of Inventions XXII-XIV would be undue.

Inventions XIV-XXI are patentably distinct because the transgenic animal of each invention comprises a distinct transgene encoding a distinct polypeptide, which has a distinct functional and phenotypic effect on the animal. The burden required to search the methods of using each transgenic animal, comprising a different transgene and having a different phenotype, would be undue.

Each of Inventions XIV-XXI and each of Inventions XXII-XXIV are patentably distinct because the methods of Inventions XIV-XXI can be used to identify modulators of BACE-1 expression or activity while the methods of Inventions XXII-XXIV are used to determine the efficacy of a treatment in vivo. The methods of Inventions XIV-XXI are not necessary for the methods of Inventions XXII-XXIV are not necessary for the methods of Inventions XIII-XXIV are not necessary for the methods of Inventions XIV-XXI. The methods of Inventions XIV-XXI and those of

Inventions XXII-XIV are classified differently. The burden required to search either of Inventions XIV-XXII together with any of Inventions XXII-XXIV would be undue.

Inventions XXII-XXIV are patentably distinct because the methods of each of the inventions are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Invention XX IIcomprises steps of detecting Aβ11-40/42 polypeptide; Invention XXIII comprises detecting BACE1 polynucleotide; Invention XXIV comprises measuring BACE1 peptide. The methods steps for each of these Inventions require different methods steps, reagents, and technical consideration. The burden required to search the methods of any of Inventions XXII-XXIV together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio Patent Examiner

> DEBORAH J. REYNOLDS SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600